UNITED STATES DISTRICT COURT
DISTRICT OF MASSACHUSETTS

UNITED STATES EX REL. KENNETH JAMES JONES Plaintiff, v. BRIGHAM AND WOMEN'S HOSPITAL, MASSACHUSETTS GENERAL HOSPITAL, MARILYN ALBERT, & RONALD KILLIANY Defendants.	)	CIVIL ACTION NO. 07-11481-WGY

MEMORANDUM

YOUNG, D.J. November 10, 2010

I. INTRODUCTION

This case presents a plethora of interesting legal theories in search of an evidentiary anchor.

Dr. Kenneth James Jones ("Relator") filed a qui tam action against the defendants Brigham and Women's Hospital, Massachusetts General Hospital ("Mass. General"), Dr. Marilyn Albert ("Dr. Albert"), and Dr. Ronald Killiany ("Dr. Killiany") (collectively, the "Defendants") under the False Claims Act, 31 U.S.C. § 3729 (the "Act"). The case arises out of alleged false statements contained in a Program Project Grant Application (the "Application") to the National Institute on Aging (the "NIA"), an

organization under the National Institutes of Health ("NIH"). The Relator alleges that certain statements contained in the Application are false because they are predicated on "falsified" data. The Relator claims that the Defendants falsely certified that the Application was in compliance with all relevant statutes and regulations. Thus, the Relator contends that the Defendants caused the government to fund the Grant in violation of the False Claims Act by asserting false statements in the Application and falsely certifying compliance with relevant statutes. The parties filed cross motions for summary judgment, which this Court now addresses.

II. BACKGROUND

A. Facts[1]

Alzheimer's Disease ("Alzheimer's") is a neurodegenerative illness associated with aging. Expert Report Andrew J. Saykin, Psy. D., 5 ¶ 1, ECF No. 83-4 ("Saykin Rep."). At the time of the alleged violations, research was being done into early detection of Alzheimer's through longitudinal studies of certain regions of the brain. The research aimed to characterize the early phase of Alzheimer's disease and to differentiate it from changes related to normal aging, thus enabling prediction of who will develop Alzheimer's years before the individual displays diagnosable

[1] This recitation is drawn from evidentiary material that is essentially undisputed. Matters in dispute are clearly stated. All inferences are drawn in favor of the Relator.

dementia. Grant Application Excerpts 2, ECF Nos. 91-1; 83-9 ("Application Excerpts").

The research at issue was conducted under a grant entitled "Age-related changes of cognition in health disease" (the "Grant"), which the NIA and the NIH first funded in 1980 and continued to fund through 2007. Dep. Marilyn Albert, Ph.D. 67:21-69:20; 82:2-5, ECF No. 83-8 ("Albert Dep."). The defendants, Drs. Albert and Killiany, along with the Relator, were part of a team of scientists working for several decades on the Grant, which consisted of four "Projects" and four "Cores." The Projects were interrelated and comprised: Neuropsychological assessment (Project 1), Single Photon Emission Computed Tomography (SPECT) (Project 2), structural magnetic resonance imaging (MRI) (Project 3), and functional magnetic resonance imaging (fMRI) (Project 4). Application Excerpts 2. The Cores provided support to the Projects and included: the Administrative and Clinical Core (Core A), the Data Management and Statistical Core (Core B), the Genetics Core (Core C), and the Neuropathology Core (Core D). Id.

The NIA systematically reviews submitted applications. The grant process requires institutions seeking funding to submit applications to the Center for Scientific Review and the NIH; the applications are then submitted to the NIA for funding consideration. Nat'l Inst. on Aging, Grant Process, available at http://www.nia.nig.gob/GrantsAndTraining/GrantProcess/, ECF No.

83-6 ("Grant Process"). The NIH Grants Policy Statement shows the initial level of review is a peer-review conducted by a committee of experts in order to assess several factors. Some of the factors include the significance of the proposed study, the approach taken, innovation, whether the investigator is appropriately trained, and whether the environment where research will be conducted will likely contribute to the probability of success. NIH Grants Policy Statement 36-37 (March, 2001), ECF No. 83-7 ("Policy Statement").

Subsequently, the Scientific Review Administrator prepares a summary statement ("Pink Sheets") with peer reviewers' comments, including a summary of the strengths and weaknesses of the proposed project and a priority score. Policy Statement 37. If recommended for further consideration, the Pink Sheets are presented to the National Advisory Council on Aging for a second level of review. Id. The Director of the NIA has the authority to approve payment of applications reviewed favorably where primary weight is given to the perceived scientific quality of the application. Grant Process.

Dr. Albert served as the Principal Investigator and Program Director of the Grant. Application Excerpts 2. The Relator was the Core Leader of Core B, the Data Management and Statistical Core. Id. As the Core B Leader, the Relator's responsibilities included supervising data management, reviewing project progress, carrying out complex analyses pertaining to individual projects,

and developing new analytic approaches for the data set. Application Excerpts 149. Dr. Mary Hyde ("Dr. Hyde") worked with the Relator as the Data Manager and Programmer for Core B. Id. Dr. Hyde's responsibilities included communicating with Project Leaders, assisting Project Leaders with data entry, and reviewing the contents of data sets for accuracy and completeness. Id.

Project 3, the structural MRI study, involved analysis of MRI images of certain regions of the brain. In the mid-1990s, with the advent of advanced MRI techniques, a potential method of early detection of Alzheimer's evolved. Saykin Rep. 7 ¶ 4. Measurements of the volumes of certain regions of interest ("ROIs") have been shown to be especially useful indicators. Id. 7 ¶ 5. Two regions of the brain, the entorhinal cortex ("EC") and the hippocampus have been shown to be indicators of the atrophy associated with Alzheimer's. Id. 6 ¶ 3. While MRI is a useful marker for degenerative changes in the brain, alone it is not a diagnostic for clinical Alzheimer's. Id. 7 ¶ 6.

In Project 3, participants were observed for a period of years to track the progression of cognitive development in the prodromal phases of Alzheimer's. Participants in the longitudinal study using MRI data were divided into three groups on the basis of their group status after several years of follow-up: Controls (subjects who remained constant for three follow-up evaluations); Questionables (non-demented subjects with memory problems who did not progress to Alzheimer's); and Converters

(non-demented subjects with memory problems who progressed and eventually were diagnosed with probable Alzheimer's). Application Excerpts 339.

Dr. Killiany was the Project Leader of Project 3, the structural MRI project. Id. 319, ECF No. 83-9. As such, he was responsible for using MRI scans to trace the boundaries of certain regions of the brain that interested the scientists, Id. 104, ECF No. 91-1; that is, he was the primary neuroanatomist tasked with tracing the boundaries of the entorhinal cortex and subsequently sending volumetric data to Dr. Hyde in the Statistical Core. Dep. Ronald J. Killiany, Ph.D. 98:10-25, ECF No. 83-12 ("Killiany Dep."). The ultimate objective of Project 3 was to determine whether structural MRI data could be used to predict which non-demented subjects with memory problems would decline into Alzheimer's. Application Excerpts 319, ECF No. 83-9.

The manual outlining of the boundaries of various regions of interest was done using a computer, a track-ball driven mouse, and a software program called "Neuroview." Killiany Answer Relator's First Set Interrogs., Answer 2, ECF No. 83-13. To trace the boundaries of the EC using the protocol developed by Dr. Killiany and other members of the Grant, the operator would begin the outline of the region at the angle formed by the junction of the rhinal sulcus and the surface of the brain. The operator would then transect this angle, cutting across the gray

matter to the level of the white matter. Next, the operator would follow the edge of the white matter to the inferior surface of the hippocampus. Finally, to complete the outline, the operator would trace the surface of the brain back to the starting point. R.J. Killiany, et al., Use of Structural Magnetic Resonance Imaging to Predict Who Will Get Alzheimer's Disease, 47 Annals of Neurology 430, 433 (2000), ECF No. 83-18 [hereinafter Killiany, Structural MRI].

The Relator alleges that Dr. Killiany falsified data pertaining to manually drawn boundaries of the EC, producing a second set of data in which the volumes of twelve subjects in the "normal" grouping were enlarged in order to make data statistically significant. Sec. Amend. Compl. ¶¶ 19-19.3, ECF No. 54. The Relator claims to have learned of this supposed second set of data through discussions with Dr. Keith Johnson, leader of Project 2, SPECT. Decl. of Kenneth Jones ¶ 9, ECF No. 86 ("Jones Decl."). This data, the Relator contends, enabled the Grant to claim that the EC was a region that could be used to predict conversion to Alzheimer's. Id. ¶ 10. In addition, the Relator claims that he compared Dr. Killiany's first and second sets of data and performed an analysis which showed that the changes Dr. Killiany made were responsible for the statistical significance of the reported results. Id.

The Relator reported his concern over a discrepancy in Dr. Killiany's two sets of data to Dr. Albert. See id. ¶ 11; Albert

Dep. 352:12-353:7. In response to the Relator's concern, Dr. Albert initiated an inquiry, having Dr. Mark Moss ("Dr. Moss"), an eminent neuroanatomist, evaluate both sets of data from twenty-three of Dr. Killiany's measurements to determine their accuracy. Albert Dep. 219:9-22, 221:20-223:5. The Relator chose the twenty-three cases evaluated by Dr. Moss. Jones Decl. ¶ 11.

B. Relator's Allegations

In total, the Relator alleges four ways in which the Defendants violated the Act. First, the Relator claims that the results generated by Dr. Killiany's altered MRI data served as the centerpiece of the Application, resulting in false representations to the NIA.[2] Jones Mot. Summ. J. 8, ECF No. 85.

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[2] Throughout the Relator's complaint, the alleged false statements are never clearly established. Despite claims sounding in fraud, he never articulated the false statements in the complaint. In order to locate the alleged false statements, the Court has had to comb through the Relator's pleadings and motions.

Theoretically, the requirements of Federal Rule of Civil Procedure 9(b) ought earlier have forestalled this exhaustive excursion. To understand why it was ultimately necessary, it is helpful briefly to rehearse the prior proceedings in this case.

The United States District Court for the District of Columbia transferred this case here on August 10, 2007. On March 27, 2009, the Defendants moved to dismiss the Relator's original Complaint because the Complaint: (1) failed to state a claim upon which relief might be granted (Fed. R. Civ. P. 12(b)(6)); (2) failed to plead fraud with particularity (Fed. R. Civ. P. 9(b)); and (3) failed to set forth concise, direct, short statements of the claim (Fed. R. Civ. P. 8(a)(2) & 8(d)(1)). Defs. Mot. Dismiss Relator's Compl. 1, ECF No. 36.

On April 17, 2009, the Relator filed a First Amended Complaint, as was his right. ECF No. 41. This rendered the Motion to Dismiss moot as it had attacked the original complaint. On May 7, 2009, the Defendants filed a Motion to Dismiss the First Amended Complaint pursuant to Federal Rules of Civil

To support this allegation, the Relator cites several statements made in the Application. He claims that the Defendants stated they "achieved a 'major finding' that measures of the [EC] were 'highly predictive' for the course of prodromal AD." Id. The Application actually states:

> Our major finding is that measures of memory and executive function, or SPECT and MRI measures of brain regions related to these domains (such as the entorhinal cortex, the hippocampus, and the caudal portion of the anterior cingulate) are highly predictive of subsequent development of dementia among non-demented individuals with memory problems.

Application Excerpts 92.

The Relator also claims that the Defendants "stated prediction of conversion to [Alzheimer's] as one of the primary findings of the MRI data, with EC studies proving to be the most 'discriminating measurements.'" Jones Mot. Summ. J. 8. The

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Procedure Rule 9(b) and 12(b)(6). ECF No. 43. On July 10, 2009, this Court dismissed the First Amended Complaint with leave to amend. Subsequently, on October 5, 2009, the Relator filed a Second Amended Complaint. ECF. No. 54. The Defendants did not challenge the present case complaint as pled; instead they moved for Summary Judgment on September 7, 2010. ECF. No. 80.

Is this the "modest" success of judicial supervision over case management of which Justice Souter complained in Bell Atlantic Corp. v. Twombly, 550 U.S. 544, 559 (2007)? Compare the hammering out of a viable complaint through successive motions to dismiss in United States ex rel. Westmoreland v. Amgen, Inc., 707 F. Supp. 2d 123 (D. Mass. 2010) and No. 06-10972-WGY, 2010 WL 3622033 (D. Mass. Sept. 20, 2010). Perhaps this is the more satisfying and cost efficient procedural approach. Either way, this Court is satisfied that in both cases the proper legal framework has been applied to the merits. The larger issues are masterfully explained in Arthur R. Miller, From Conley to Twombly to Iqbal: A Double Play on the Federal Rules of Civil Procedure, 60 Duke L.J. 1 (2010).

actual Application, however, says: "The most discriminating MRI measures pertain to atrophy of the medial temporal lobe (particularly the entorhinal cortex), and the volume of anterior and posterior cingulate." Application Excerpts 100. Further, the Relator claims that the Defendants wrote that they had "identified a selected group of brain regions, primarily the EC, which paralleled the neuropsychological changes during preclinical [Alzheimer's]." Jones Mot. Summ. J. 8. But the Application states:

> [A] selected group of brain regions develop neuropathology during preclinical [Alzheimer's] which, in turn, influence the cognitive deficits of the individuals. Based on combined analyses of the data it appears that problems within a memory circuit (involving the entorhinal cortex and the hippocampus) are essential but not sufficient for a diagnosis of [Alzheimer's] . . . .

Application Excerpts 101. These statements together account for the allegedly false statements, predicated on "falsified" data, which comprise the Relator's first claim.

Second, the Relator alleges the Defendants violated the Act by falsely stating that Dr. Killiany followed blinded methodologies when manually tracing the EC. The Application states in relevant part: "In order to prevent possible bias in the drawing of the manually drawn regions, all operators are blinded to the groupings of the subjects." Application Excerpts 350. The Relator admits, however, that he has no evidence that Dr. Killiany had not followed proper, blinded methodologies when

retracing EC boundaries. Dep. Kenneth J. Jones 164:14-19, ECF No. 83-2 ("Jones Dep.").

The third basis for the Relator's claim is that the Defendants violated the Act by making false representations that they had conducted a reliability study on the underlying data. Sec. Amend. Compl. ¶ 29.1. Section D4.3 of the Application states, "The procedures in place for generating the manually drawn image maps have been demonstrated to have high reliability. Inter-rater reliability for these ROIs ranges between r=0.94-0.99." Application Excerpts 350. The Relator contends that the reliability study represented in the Application was based on the first set of data, not the second, "falsified" set of data. Jones Decl. ¶ 10.

Contemporaneous emails show that Dr. Killiany submitted the second set of data to Dr. Hyde for reliability testing. Aff. Lisa A. Tenerowicz, Exs. 9, 10, ECF Nos. 97-9, 97-10. In addition, Dr. Killiany testified that he had no knowledge of the statistical significance of the MRI data nor what happened to the EC tracings once the measurements were emailed to Dr. Hyde. Killiany Dep. 60:7-61:1, 162:14-19.

The Relator also raises a fourth novel claim in his motion for summary judgment that was not originally pled in his Second Amended Complaint. In the motion, the Relator claims that the Defendants violated the Act by both expressly and impliedly certifying compliance with the "Responsibilities of Awardee and

Applicant Institutions for Dealing with and Reporting Possible Misconduct in Science" ("Responsibilities of Applicants"), 42 C.F.R. Part 50, Subpart A (2001) (replaced by 42 C.F.R. Part 93).

Additionally, the Relator filed a motion for sanctions for spoliation of evidence on September 28, 2010, asserting yet another theory of liability for violating 45 C.F.R. § 74.53, a separate regulation regarding post-award requirements.

III. ANALYSIS

A. Legal Standard

Summary judgment is proper where there exists no genuine issue of material fact and where the moving party is entitled to judgment as a matter of law based on the pleadings, depositions, answers to interrogatories, admissions on file, and any affidavits. Dennis v. Osram Sylvania, Inc., 549 F.3d 851, 855 (1st Cir. 2008). The moving party bears the initial burden of showing the district court the basis for its motion and identifying where there exists a lack of any genuine issue of material fact. Celotex Corp. v. Catrett, 477 U.S. 317, 323 (1986). The burden of going forward then shifts to the nonmoving party to show sufficient evidence to back up each element of each claim. See id. at 324.

Where the nonmoving party cannot show sufficient evidence to establish an essential element of a claim, there can be no genuine issue of material fact "since a complete failure of proof

concerning an essential element of the nonmoving party's case necessarily renders all other facts immaterial." Id. at 323. Additionally, "[w]here the record taken as a whole could not lead a rational trier of fact to find for the non-moving party, there is no 'genuine issue for trial.'" Matsushita Elec. Indus. Co. v. Zenith Radio Corp., 475 U.S. 574, 587 (1986) (quoting First Nat'l Bank of Ariz. v. Cities Service Co., 391 U.S. 253, 288 (1968)). Finally, in determining whether summary judgment is appropriate, all reasonable inferences must be drawn in favor of the non-moving party. Id. at 587.

B. False Claims Act Theories

The False Claims Act creates civil liability for individuals or entities that make false or fraudulent claims for payment to the federal government. See 31 U.S.C. § 3729(a). An individual violates the Act when he "knowingly presents, or causes to be presented, a false or fraudulent claim for payment or approval" to an officer or employee of the United States Government. 31 U.S.C. § 3729(a)(1)(A). An action may be filed by the Attorney General or by a private individual, called a relator, as an assignee of the government. 31 U.S.C. § 3730(a)-(b).

In order to state a claim under the Act, an individual must allege that the defendant: "(1) knowingly presented or caused to be presented, (2) a false claim, (3) to the United States government, (4) knowing its falsity, (5) which was material, (6)

seeking payment from the federal treasury." United States ex rel. Hutcheson v. Blackstone Med., Inc., 694 F. Supp. 2d 48, 61 (D. Mass. 2010). Here, the "false claim or statement," "materiality," and "knowingly" elements are at issue with respect to the Relator's claims.

There are three theories under which a claim may be "false or fraudulent" under the Act. These are: (1) factual falsity;[3] (2) legal falsity under an express certification theory;[4] and (3) legal falsity under an implied certification theory.[5] It was not clear from the Second Amended Complaint or the Relator's summary judgment memoranda upon which theory he relied. At oral argument, Relator's counsel clarified that the claims rest on all three theories. Thus, misrepresentations regarding the allegedly

[3] A claim is deemed "factually false" when "the goods or services provided are either incorrectly described, or make claim for a good or service never provided." Hutcheson, 694 F. Supp. 2d at 62 (citing United States ex rel. Mikes v. Straus, 274 F.3d 687, 697 (2d Cir. 2001)).

[4] A claim is legally false under an express certification theory when the party making the claim expressly but falsely states that it has complied with any precondition of payment. Hutcheson, 694 F. Supp. 2d at 62 (citing United States ex rel. Conner v. Salina Reg'l Health Ctr, Inc., 543 F.3d 1211, 1217 (10th Cir. 2008)).

[5] In Hutcheson, the Court recognized that a claim is legally false under an implied certification theory when "a claimant makes no express statement about compliance with a statute or regulation, but by submitting a claim for payment implies that it has complied with any preconditions to payment." Id. (citing Conner, 543 F.3d at 1218). In adopting this definition, the Court restricted liability under an implied certification theory to "compliance with expressly stated preconditions of payment found in the relevant statute or regulations." Id. at 63 (citing Mikes, 274 F.3d at 700).

falsified data, blinded methodologies, and reliability tests arise under the factual falsity theory. Alleged failure to comply with the Responsibilities of Applicants grounds liability under both the express and implied certification theories. Finally, the alleged failure to comply with the Post-award Requirements regulation appears to be grounded upon an implied certification theory.

C. Application

1. Falsified Data

At oral argument, Relator's counsel devoted the majority of his time to arguing that the evidence irrefutably showed that the EC data was falsified. The Relator, however, failed to articulate how the supposedly false data relates to a false statement in the Application. There is no evidence suggesting that the EC data itself was submitted as part of the Application. At most, the Relator identified three statements in the Application which depended on the allegedly false data.[6] Each of the statements identified by the Relator expresses a conclusion drawn from the data that the Relator alleges was falsified. The

[6] The Relator contends that the Defendants made false representations regarding "major findings." The allegedly false representations claimed a major finding that some regions of the brain, including the entorhinal cortex, are highly predictive of conversion to Alzheimer's. Application Excerpts 92. Furthermore, the EC was identified, among others, as a particularly discriminating region. Id. 100. Finally, the Application also stated that the EC was among several brain regions that developed neuropathology during preclinical Alzheimer's. Id. 101.

difficulty with this claim is that the creation of the underlying data — the measurements of the entorhinal cortex — requires considerable scientific judgment.

At a minimum, "falsity" under the Act requires proof of an objective falsehood. United States ex rel. Roby v. Boeing Co., 100 F. Supp. 2d 619, 625 (S.D. Ohio 2000) (citing Hagood v. Sonoma Cnty. Water Agency, 81 F.3d 1465, 1477-78 (9th Cir. 1996)). "Expressions of opinion, scientific judgments, or statements as to conclusions about which reasonable minds may differ cannot be false." Id.; see also United States ex rel. Milam v. Regents of the Univ. of Cal., 912 F. Supp. 868, 886 (D. Md. 1995) (noting that "the legal process is not suited to resolving scientific disputes or identifying scientific misconduct").

The Defendants assert that the central issue of the claim is the manual tracing of the EC. Dr. Killiany, the Relator, and the experts for both parties have submitted affidavits averring that the manual tracing of the EC is a subjective process during which the exercise of scientific judgment is used at almost every step. Jones Dep. 157:5-12; Killiany Dep. 49:1-6; Saykin Rep. 16 ¶ 15. Moreover, there is agreement in the scientific community that the EC is a particularly difficult region to trace. Saykin Rep. 13-16 ¶¶ 11-13; Expert Report Dr. Schuff 2, ECF Nos. 83-17; 91-6 ("Schuff Rep."). The Application explicitly notes differing

boundary definitions regarding certain regions of interest ("ROIs"), including the entorhinal cortex. Application Excerpts 348-49. After the boundary of the EC is manually drawn, a semi-automated computer program calculates the total intracranial volume of the EC. Killiany, Structural MRI, at 432. The manual tracing is used to calculate volumetric data, which is obtained objectively by a computer program. The Relator himself admitted that drawing the boundaries of the EC is "subjective because it relies on the operator's knowledge of anatomy, knowledge of the boundaries, and eyesight, so it would require a good deal of practice and training [to trace ROIs]." Jones Dep. 157:5-12.

Relator's counsel insisted at oral argument that this is not an issue of scientific dispute because the scientific dispute involves the decision as to which protocol to use; since the same protocol was used and the results were inconsistent, the second set must have been falsified or manipulated. Moreover, he argued, because the volumetric data is derived objectively from boundaries traced using the same protocol, there is no scientific judgment at issue in this case. Relator's counsel, however, glossed over the undisputed fact that tracing the EC is highly subjective and thus two scientists who use the same protocol manually to trace the EC may nevertheless obtain different results. The parties both submitted expert reports to substantiate their positions as to whether Dr. Killiany's tracing of the EC was more accurate in the first or second set of data.

Not surprisingly, the experts reached contrary conclusions. See Saykin Rep. 14 ¶ 11; Schuff Rep. 4.

In this case, the disagreement over which set of data was more accurate cannot give rise to a "false" or "fraudulent" statement. The record demonstrates that the act of tracing the boundaries of the EC is subjective and requires the exercise of scientific judgment. Disagreements over these judgments are not the proper basis for a claim under the Act. Luckey v. Baxter Healthcare Corp., 2 F. Supp. 2d 1034, 1047-48 (N.D. Ill. 1998) (holding that a dispute over the exercise of "scientific judgment" is "insufficient to support an FCA action"); see also United States ex rel. Prevenslik v. Univ. of Wash., Civ.A. MJG-02-80, 2003 WL 23573424, at *4 (D. Md. June 20, 2003) ("[A] difference in the interpretation of research results and data with regard to a scientific phenomenon subject to a great debate within the scientific community is not an appropriate basis for an FCA claim.").

Furthermore, where experts disagree over the accuracy of Dr. Killiany's second set of data, such disagreement does not yield a resolution where one can state with reasonable certainty that one conclusion is true and the other false. Boisjoly v. Morton Thickol, Inc., 706 F. Supp. 795, 810 (D. Utah 1988) ("[T]he [certification] reflects an engineering judgment . . . . It is clearly not a statement of fact that can be said to be either true or false, and thus cannot form the basis of an FCA claim.").

Accordingly, this Court holds that the basis for the Relator's claim regarding falsified data is a scientific dispute over the accuracy of subjective measurements, and is thus insufficient to support a claim under the Act.

2. Blinded Methodologies

The Relator contends that the Defendants made false statements representing that Dr. Killiany followed blinded methodologies when manually tracing the EC. The Application states, in relevant part: "In order to prevent possible bias in the drawing of the manually drawn regions, all operators are blinded to the groupings of the subjects . . . ." Application Excerpts 350.

Ample record evidence shows that Dr. Killiany was, in fact, blinded to the group status of the participants for which he re-traced the boundaries of the EC. Dr. Killiany was also blinded to the statistical significance of any data he produced. Furthermore, Dr. Killiany did not receive information concerning the data going to the statistical core, nor was he involved in the analysis of that data. Albert Dep. 275:20-276:3; Killiany Dep. 60:7-61:1, 162:14-19; Dep. Keith A. Johnson 114:1-116:11, 211:13-212:14, ECF No. 83-19 ("Johnson Dep."). Finally, the Relator himself admitted at his deposition that he has no evidence that Dr. Killiany was not following proper, blinded methodologies when retracing EC boundaries. Jones Dep. 164:14-

19. There is no genuine issue of material fact as to this matter. The Relator has presented no evidence from which a reasonable finder of fact could conclude that Dr. Killiany was not blinded, so summary judgment for the Defendants on this issue is appropriate.

3. Reliability Study

The Relator alleges that a statement in the Application regarding a reliability study was false because the reliability study analyzed the first set of data from the EC, while the substance of the Application relied upon the second set of EC data. He cites language in the Application, which says that "[t]he procedures in place for generating the manually drawn image maps have been demonstrated to have high reliability. Inter-rater reliability for these ROIs ranges between r=0.94-0.99 (Sandor et al., 1992; Killiany et al., 1993; Killiany et al., 2000)." Application Excerpts 350.

The record largely is silent on the reliability study. The only evidence of record comes from the Relator's declaration. He states: "The initial MRI data was the data that had been subject to our reliability study, using blinded, experienced raters and producing a high coefficient of reproducibility." Jones Decl. ¶ 10. The Relator claims that when a reliability study is done using the second set of data, the Pearson Correlation coefficient drops from the reported 0.96 to 0.54. Id. ¶ 21. As the lead

statistician for Core B, the Relator likely is qualified to provide expert testimony regarding a reliability study. See Fed. R. Evid. 702. It is not clear, however, that the Relator has put himself forth as an expert consistent with Rule 26(a)(2) of the Federal Rules of Civil Procedure. His testimony is also bereft of sufficient information to evaluate the veracity of his opinion. He did not cite evidence in the record that substantiates his claim that the reliability study was conducted on the initial set of data. Nor does he explain how he knows which study subjects were chosen for the reliability study. Thus, the Relator provides no foundation upon which the Court may accept his conclusion.

To the extent the Relator offers himself as a lay witness, he does not provide sufficient competent evidence of his personal knowledge. See Fed. R. Evid. 601. The Relator admitted in his deposition that "almost a hundred percent" of the data he received concerning Dr. Killiany's project came from Dr. Hyde. Jones Dep. 96:19-97:5. Furthermore, the Relator's affidavit fails to establish personal knowledge because it contains no evidence pertaining to critical issues surrounding the reliability study; these issues include when and how the reliability study was conducted, who randomly selected the twenty-five subjects for the study, and who actually conducted the study. The chart provided by the Relator points to no

evidence concerning the actual selection of subjects for the reliability study. Whether testifying as an expert or as a lay witness, the Court surmises that the Relator simply expects the Court to accept his conclusions sola fide. Without sufficient foundation for his conclusions, the evidence provided by the Relator in his declaration amounts only to hearsay. See Fed. R. Evid. 801(c). Thus the Court need not give any weight to the representations provided in the Relator's declaration pertaining to the reliability study.

The Relator also fails to satisfy the materiality element with respect to the statements concerning the reliability study. He relies on the testimonies of Dr. Schuff and Dr. Dávila-García in attempt to establish that the reliability study was material to NIH's decision to fund the Grant. In his report, Dr. Schuff notes that "the statements indicate in my opinion that the issue of reliability and objectivity of the measurements, specifically with respect to the [EC], were material to the reviewer's judgment on the feasibility and scientific merit of study." Schuff Rep. 6. Dr. Schuff, however, is not qualified to testify regarding the materiality of statements to the NIH's decision to fund the Grant because he is not an expert in that area. See Fed. R. Evid. 702.

Rule 26 of the Federal Rules of Civil Procedure requires that any witness intended to provide expert testimony must submit

a written report which includes his or her qualifications as an expert. Fed R. Civ. P. 26(a)(2)(B)(iv). In his report, Dr. Schuff lists his qualifications as a professor of radiology in the Department of Radiology and Biomedical Imaging at the University of California in San Francisco, an investigator at the VA Medical Center, a lead physicist at the Center for Imaging of Neurodegenerative Diseases at the VA Medical Center, and a researcher focusing on the development of new MRI methods and concepts to identify markers of neurodegenerative diseases, including Alzheimer's. Schuff Rep. 1. Dr. Schuff does not, however, list any qualifications regarding the NIH application review process or the peer editing process, and he cannot testify as to the materiality of a statement regarding the NIH review process.[7]

Dr. Dávila-García appears qualified to opine on the matter. See Decl. Martha Isabel Dávila-García, Ph.D., ¶ 4, ECF No. 84 ("Dávila-García Decl."). Her declaration does support the claim that the reliability study was material to NIH's decision to fund the Grant. Dr. Dávila-García states that "[r]eviewers would not provide priority scores for an application that relied upon falsified preliminary data, that had made false statements about

[7] At oral argument, Relator's counsel adamantly argued that Dr. Schuff was more than qualified to testify about matters concerning the NIH review process, but did not provide any examples of past experience that would so qualify him.

methodologies followed or that failed to disclose allegations of scientific misconduct on any one grant proposal." Id. ¶ 10. Furthermore, Dr. Dávila-García refers to the statement in the application about the Pearson Coefficient and states that its inclusion was "required" in the Application and "fundamental to the peer review ranking of the application." Id. ¶ 12.

Federal Rule of Evidence 702, however, requires that the opinions provided in expert testimony be supported by sufficient facts or data. Fed. R. Evid. 702. Although Dr. Dávila-García claims that the reliability study was material, she does not support her opinion with any evidence from the record. See Advo, Inc. v. Phila. Newspapers, Inc., 51 F.3d 1191, 1198 (3d Cir. 1995) (indicating expert testimony without factual foundation cannot defeat a motion for summary judgment); see also Virgin Atl. Airways Ltd. v. British Airways PLC, 69 F. Supp. 2d 571, 579 (S.D.N.Y. 1999) ("[A]n expert's opinion is not a substitute for a plaintiff's obligation to provide evidence of facts that support the applicability of the expert's opinion to the case.").

Dr. Dávila-García opines that the reliability analysis was material because it was a required element of the application. She does not, however, provide any support for this statement from a statute, regulation, instruction manual, or even personal experience. Moreover, Dr. Dávila-García fails to cite any of the reviewers' comments from the Pink Sheets regarding the strengths

and weaknesses of the Application. Her opinion is thus completely without corroborating evidentiary support. In fact, the Defendants aptly note that the record actually contradicts her contention that the reliability study was material to the NIH's decision to fund the Grant. There is only one mention of the reliability study in the Pink Sheets: "[T]he use of Pearson correlation coefficients and Student t-tests to assess reliability, as proposed, is inadequate." Pink Sheets 32, ECF No. 83-22. Thus, the expert testimony of Dr. Dávila-García is not properly supported by relevant facts from the record.

In addition, the Relator has not established the knowledge element of the claim. As discussed above, the record is silent as to whether the reliability study was conducted on the second set of data and whether the reference to the Pearson Coefficient related to the first or second set of data. Beyond this, there is no evidence whatsoever on the record that any of the Defendants knew that the statement regarding the Pearson Coefficient was inaccurate.

The Court holds that the Relator has failed to establish the falsity or materiality of the statement regarding the reliability study in the Application or that any of the Defendants had any knowledge of any inaccuracy. Therefore, the Court awards summary judgment to the Defendants regarding this claim.

4. Responsibilities of the Applicant: 42 C.F.R. Part

50, Subpart A

a. Express Certification

In his motion for summary judgment, the Relator alleges that the Defendants violated the Act by expressly certifying in the Application that they "accepted the obligation to comply with Public Health Service terms and conditions if a grant is awarded as a result of this application." Application Excerpts, Face Page. The Application contains two acceptances, one signed by the Principal Investigator, Dr. Albert, and one signed by the organization, Mass. General; these constitute the express certifications. The Principal Investigator's Acceptance states:

> I certify that the statements herein are true, complete and accurate to the best of my knowledge. I am aware that any false, fictitious, or fraudulent statements or claims may subject me to criminal, civil, or administrative penalties. I agree to accept responsibility for the scientific conduct of the project and to provide the required progress reports if a grant is awarded as a result of this application.

Id. This statement was signed by Dr. Albert on October 1, 2001. On the same day, Marcia L. Smith signed the "Applicant Organization Certification and Acceptance" on behalf of Mass. General. The Organization's Acceptance states:

> I certify that the statements herein are true, complete and accurate to the best of my knowledge, and accept the obligation to comply with Public Health Service terms and conditions if a grant is awarded as a result of this application. I am aware that any false, fictitious, or fraudulent statements or claims may

> subject me to criminal, civil, or administrative penalties.

Id.

The Relator contends that these statements were false because the Defendants were not in compliance with 42 C.F.R. Part 50, a regulation concerning the responsibilities of applicant institutions in connection with allegations of misconduct involving the funding.[8] Subpart A of the regulation stipulated that the responsibilities of the applicant institution are such that it shall "submit, along with its annual assurance, such aggregate information on allegations, inquiries, and investigations as the Secretary may prescribe." 42 C.F.R. § 50.103(b)(2)(2001).

Additionally, Section 50.103(d)(1) required that "[a] written report shall be prepared that states what evidence was reviewed, summarizes relevant interviews, and includes the conclusions of the inquiry." 42 C.F.R. § 50.103(d)(1)(2001). The Relator asserts that because Dr. Albert did not report any investigation in connection with the allegations of scientific misconduct reported by the Relator, the Defendants accepted funding in violation of the Responsibilities of Applicants;

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[8] In May of 2005, a final rule removed 42 C.F.R. Part 50 and replaced it with a more comprehensive regulation entitled, "Public Health Service Policies on Research Misconduct." 70 Fed. Reg. 28370 (May 17, 2005)(codified at 42 C.F.R. Part 93).

therefore, noncompliance with this regulation at the time of submission of the Application violated the Act.

The Relator's theory of express certification relies on the "Applicant Organization Certification and Acceptance." See Application Excerpts, Face Page. The acceptance states that the obligation to comply with Public Health Services terms and conditions is contingent upon receipt of funding. Compliance, therefore, is forward-looking. Specifically, compliance would begin in July 2002 (when the funding began) and not in October of 2001 (when the Application was submitted). Because the conduct at issue occurred in 2001, prior to the Application's submission, the Relator theoretically could argue that the Defendants are in violation of past grant applications, assuming such applications contained similar language. The Relator does not introduce any evidence of application certifications from the 1997-2002 funding cycle, and therefore, provides no evidence that the regulation was applicable.

Furthermore, the certification at issue is too vague to support a claim under an express certification theory. Where an express certification claim relies on failure to comply with a statute, regulation, or some other process, the certification language must explicitly require compliance with that specific statute, regulation, or process. See Hutcheson, 694 F. Supp. 2d

48 at 66 n.13 (holding that providers expressly certified compliance with the Anti-Kickback Statute by signing a certification that specifically referred to that statute). This Court has previously ruled that vague certifications, such as the one at issue here, are inadequate for express certification claims. United States ex rel. Westmoreland v. Amgen, Inc., 707 F. Supp. 2d 123, 136-37 (D. Mass. 2010) (holding that "broad language requiring compliance with 'all applicable state and federal laws' is insufficient to constitute an express certification of compliance with [a specific statute]."); see also Hutcheson, 694 F. Supp. 2d at 66 n.13 ("The actual certification in the Hospital Cost Report is not specific enough to create False Claims Act liability for failure to comply with the Anti-Kickback Statute, as it refers broadly to 'such laws and regulations.'"). Because the certification is forward-looking and overly broad, there is no liability under an express certification theory.

b. Implied Certification

The Relator insists that if the Court does not hold the Defendants in violation of the Act under an express certification theory, then the Defendants must be found liable under a theory of implied certification for falsely certifying compliance with the Responsibilities of Applicants.

As explained above, allegations regarding the Responsibilities of Applicants regulation were raised for the first time in the Relator's summary judgment motion. While the Second Amended Complaint referenced an express certification theory for false statements, no mention of an implied certification theory of liability was made until the Relator filed his motion for summary judgment on September 15, 2010. The claim under an implied certification theory is based on allegations that the Defendants did not follow an investigating procedure under the Responsibilities of Applicants, whereas the original claims in the Second Amended Complaint were based on allegations of falsified data and submissions of false statements predicated on that data. While related, the factual record for these new claims would be substantially different.

Furthermore, the Relator makes new allegations in 2010 regarding conduct that may have occurred in 2001. The Relator's original Complaint was filed on June 14, 2006, just within the six year statute of limitations period for a claim under the False Claims Act. 31 U.S.C. § 3731(b)(1). To allow the Relator effectively to amend his complaint almost four years later to include an allegation dependant on different evidence would be unduly prejudicidal to the Defendants.

Moreover, even if the Court allowed this claim to go forward, it would not survive summary judgment. In Hutcheson, the Court observed that a claim may be legally false when "a claimant makes no express statement about compliance with a statute or regulation, but by submitting a claim for payment implies that it has complied with any preconditions to payment." Hutcheson 694 F. Supp. 2d at 62. Arguably, as recipients of NIH funding in the past, see Albert Dep. 67:21-69:20, the Defendants should have been aware of any regulations with which they were required to comply as a prerequisite for payment of funds. Per Hutcheson's requirement that the regulation explicitly state compliance as a precondition for payment, this regulation states: "An institution's failure to comply with its assurances and requirements of this subpart may result in enforcement action against the institution, including loss of funding . . . ." 42 C.F.R. § 50.105 (2001).

According to the regulation, once scientific misconduct is suspected or alleged, an applicant institution must take "immediate and appropriate action." 42 C.F.R. § 50.103(c)(3)(2001). An inquiry into any allegation of scientific misconduct must be completed within sixty calendar days; "[a] written report shall be prepared that states what evidence was reviewed, summarizes relevant interviews, and includes the conclusions of the inquiry." Id. § 50.103(d)(1). The regulation

further stipulates that the Director of the Office of Scientific Integrity shall be notified only when "on the basis of the initial inquiry, the institution determines that an investigation is warranted." Id. § 50.103(d)(4); see also id. § 50.104(a)(1). Finally, the regulation demands secure maintenance of sufficiently detailed documentation of inquiries for at least three years after the inquiry's termination. Id. § 50.103(d)(6).

According to the Relator, he first made Dr. Albert aware of his concerns about the data on March 15, 2001. Jones Decl. ¶ 11. Notably, the Relator did not accuse Dr. Killiany of scientific misconduct; rather, he voiced concern that there was a discrepancy between the two sets of data that he could not resolve and that it was a serious matter requiring action. Jones Dep. 238:14-239:10.

At that point, the Relator suggested Dr. Albert secure an independent evaluation of the circumstances leading up to the second set of data. He then provided Dr. Albert with a list of twenty-three cases that he believed to be suspect. Jones Decl. ¶ 11. Dr. Albert engaged Dr. Moss to re-evaluate the data. Id. ¶ 12. Thus, it is undisputed that an inquiry was performed regarding the discrepancy between the two sets of data.[9] The

[9] The Relator introduced his declaration and an expert declaration suggesting that the inquiry was inadequate because it was not done by an independent evaluator. Neither declaration identifies any part of the regulation that requires the inquiry

only evidence available regarding the next steps taken is testimonial; documentary evidence no longer exists. Dr. Johnson was satisfied with the results of the inquiry. Johnson Dep. 198:4-22, 205:24-206:6. Dr. Albert, also satisfied with Dr. Moss's evaluation, considered the issue resolved because it was no longer discussed. Albert Dep. 233:6-234:1, 363:7-16. The Relator did not produce any objective evidence which would suggest that a formal investigation was warranted beyond the initial inquiry. The record does not contain sufficient evidence to show that the Defendants failed to comply with the Responsibilities of Applicants; therefore this claim does not survive summary judgment.

5. Motion for Sanctions for Spoliation of Evidence

On September 28, 2010, the Relator filed a motion for sanctions for spoliation of evidence against Mass. General for "destroying essential documents and critical evidence" pertaining to the inquiry into the revision of the EC data. Memo L. Supp. Relator's Mot. Sanctions Spoliation Evid. 2, ECF No. 100. The Responsibilities of Applicants requires the retention of documents related to inquiries for only three years, thus Mass.

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be done by an outside, independent evaluator. That the Relator was not satisfied with the person chosen by the Principal Investigator to conduct the inquiry is of no consequence to this Court because it is not supported by a requirement in the regulation.

General legally could have disposed of any such documents in 2004.

The Relator argues that Mass. General violated yet another regulation by failing to maintain its records through 2010. The regulation, "Post-award Requirements," pertaining to the retention and access requirements for records, states in relevant part: "Financial records, supporting documents, statistical records, and all other records pertinent to an award shall be retained for a period of three years from the date of the final . . . submission of the . . . annual financial report." 45 C.F.R. § 74.53(b). The regulation further stipulates that if litigation begins prior to the expiration of the three-year period, "records shall be retained until all litigation, claims or audit findings involving the records have been resolved and final action taken." 45 C.F.R. § 74.53(b)(1).

Again, compliance with the Post-award Requirements regulation is forward-looking. Because the alleged violations of the Responsibilities of Applicants regulation took place in 2001 and the Grant was not funded until 2002, the Post-award Requirements do not apply to the inquiry.[10] The conduct at issue

[10] In the Relator's motion for sanctions for spoliation of evidence, he contends the Defendants violated two regulations, both the Responsibilities of Applicants and the Post-award Requirements, under an express certification theory based on the Acceptance signed by Mass. General in the 2001 Grant application which broadly covered the entire application. Again, under

occurred within the 1997-2002 funding cycle. Accordingly, Mass. General was required to retain records from that funding cycle until 2005. Since the three-year retention period had expired by 2007, when the original suit was brought, there is no basis for sanctions for spoliation of evidence.

IV. CONCLUSION

Accordingly, on October 6, 2010, the Defendants' motion for summary judgment [ECF No. 80] was GRANTED, the Relator's motion for summary judgment [ECF No. 85] was DENIED, and judgment entered for the Defendants on the same day. Relator's motion for sanctions [ECF No. 100] was also denied.

/s/ William G. Young

WILLIAM G. YOUNG
DISTRICT JUDGE

Amgen, this express certification is too vague to create liability on behalf of the signatory. See Amgen, 707 F. Supp. 2d at 136-37.

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1:07-cv-11481-WGY Jones et al v. Brigham and Women's Hospital et al
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